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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/615,797

Applicant: ROBERTS, et al.

Filed: July 10, 2003

Art Unit: 1616

Examiner: Alton N. Pryor

Title: METAL COMPOUNDS, MIXED OR  
SULPHATED, AS PHOSPHATE  
BINDERS

Docket No.: 40304772

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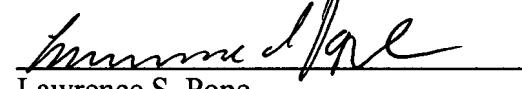
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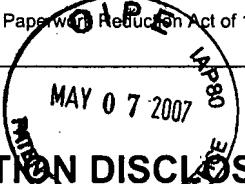
Respectfully submitted,

  
Lawrence S. Pope  
Reg. No. 26,791

Date: May 8, 2007

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 <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Not for submission under 37 CFR 1.99)</p>	Application Number	10615797
	Filing Date	2003-07-10
	First Named Inventor	Roberts et al.
	Art Unit	1616
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### U.S.PATENTS

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	1	6039981		2000-03-21	Woo et al.	
	2	6596311		2003-07-22	Dobetti	
	3	6576665		2003-06-10	Dennett, Jr. et al.	
	4	5651997		1997-07-29	Makino et al.	
	5	5213794		1993-05-25	Fritsch et al.	
	6	6733780		2004-03-11	Tyler et al.	
	7	6696087		2004-02-24	Matsuda et al.	
	8	3395211		1968-07-30	Wielich et al.	

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	9	4254099		1981-03-03	Asmussen et al.	
	10	4609543		1986-09-02	Morris et al.	
	11	6448323		2002-09-10	Jordan et al.	
	12	6794367		2004-09-21	Tanida et al.	
	13	6794864		2004-06-15	Makino et al.	
	14	5656080		1997-08-12	Staniforth et al.	
	15	5817340		1998-10-06	Roche et al.	
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	17	3650704		1972-03-21	Kumura et al.	
	18	3879523		1975-04-22	Miyata et al.	
	19	6028023		2000-02-22	Vierheilig	

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	20	6790895		2004-09-14	Stelandre et al.	
	21	4351814		1982-09-28	Miyata et al.	
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	1	20020122786		2002-09-05	Matsuda et al.	
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	1	1304104	EP		2003-04-23	Matsuda et al.		<input type="checkbox"/>
	2	95/29679	WO		1995-11-09	Katdare et al.		<input type="checkbox"/>
	3	99/44580	WO		1999-09-10	Dobetti et al.		<input type="checkbox"/>
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	5	03/092658	WO		2003-11-13	Fekete et al.		<input type="checkbox"/>
	6	03/017980	WO		2003-03-06	Sugaya et al.		<input type="checkbox"/>
	7	03/028706	WO		2003-04-10	Hibino et al.		<input type="checkbox"/>
	8	10236960	JP		1998-09-08	Kudo et al.		<input type="checkbox"/>
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	12	2005/009381	WO		2005-02-03	Phillips et al.		<input type="checkbox"/>
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	1	STAMATAKIS et al., Influence of pH on In Vitro Disintegration of Phosphate Binders, American Journal of Kidney Diseases, Vol. 32, No. 5 (November 1998) p808-812	<input type="checkbox"/>
	2	BADAWY et al., Effect of Drug Substance Particle Size on the Characteristics of Granulation Manufactured in a High-Shear Mixer, AAPS PharmSciTech, Vol. 1, No. 4 (2000) article 33	<input type="checkbox"/>
	3	ROBLOT et al., Effect of Lubricant Level and Applied Compressional Pressure on Surface Friction of Tablets, Journal of Pharmaceutical Sciences, Vol. 74, No. 6 (June 1985) p697-699	<input type="checkbox"/>
	4	BOLHUIS et al., Interaction of Tablet Disintegrants and Magnesium Stearate during Mixing I: Effect on Tablet Disintegration, Journal of Pharmaceutical Sciences, Vol. 70, No. 12 (December 1981) p1328-1330	<input type="checkbox"/>
	5	KAPLAN et al., A Preference Study: Calcium Acetate Tablets versus Gelcaps in Hemodialysis Patients, Nephrology Nursing Journal, Vol. 29, No. 4 (August 2002) p363-365	<input type="checkbox"/>
	6	MURTHY et al., Effect of Shear Mixing on In Vitro Drug Release of Capsule Formulations Containing Lubricants, Journal of Pharmaceutical Sciences, Vol. 66, No. 9 (September 1977) p1215-1219	<input type="checkbox"/>
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8	SUREN G., Evaluation of lubricants in the development of tablet formula, Dansk Tidsskr. Farm., Vol. 45 (1971) p331-338	<input type="checkbox"/>
9	VITKOVA et al., The use of some hydrophobic substances in tablet technology, Acta Pharmaceutica Hungarica, Vol. 68 (1998) p336-344	<input type="checkbox"/>
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11	VATIER et al., Antacid Activity of Calcium Carbonate and Hydrotalcite Tablets, Arzneim-Forsch./Drug Res., 44(I), Nr. 4 (1994) p514-518	<input type="checkbox"/>
12	BROUWERS et al., De invloed van de toedieningsvorm op de werkingsduur en op het pH-bereik bij antacida; een in-vitro- en in-vivo-studie, Pharmaceutisch Weekblad 111-1976, p1244-1248	<input type="checkbox"/>
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	19	HIBINO et al., Calcination and rehydration behavior of Mg-Fe-CO <sub>3</sub> hydrotalcite-like compounds, Journal of Materials Science Letters, Vol. 19 (2000) p1403-1405	<input type="checkbox"/>
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	21	ARCO et al., Effect of the Mg: Al Ratio on Borate (or Silicate)/Nitrate Exchange in Hydrotalcite, Journal of Solid State Chemistry, Vol. 151 (2000) p272-280	<input type="checkbox"/>
	22	FROST et al., Thermal Decomposition of Synthetic Hydrotalcites Reevesite and Pyroaurite, Journal of Thermal Analysis and Calorimetry, Vol. 76 (2004) p217-225	<input type="checkbox"/>
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	32	MIYATA, Physico-chemical properties of synthetic hydrotalcites in relation to composition, Clays and Clay Materials, Vol. 28, No. 1 (1980) p50-56	<input type="checkbox"/>
	33	BARRIGA et al., Hydrotalcites as sorbent for 2,4,6-trinitrophenol: influence of the layer composition and interlayer anion, J. Mater. Chem., Vol. 12 (2002) p1027-1034	<input type="checkbox"/>
	34	TICHIT et al., Catalysis by hydrotalcites and related materials, Cattech, Vol. 7, No. 6 (2003) p206-217	<input type="checkbox"/>
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	36	RAJAMATHI et al., Reversible thermal behavior of the layered double hydroxide of Mg with Al: mechanistic studies, Journal of Materials Chemistry, Vol. 10 (2000) p 2754-2757	<input type="checkbox"/>
	37	HANSEN et al., Synthesis and characterization of pyroaurite, Applied Clay Science, Vol. 10 (1995) p5-19	<input type="checkbox"/>
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	39	BOLOGNINI et al., Mg/Al mixed oxides prepared by coprecipitation and sol-gel routes: a comparison of their physico-chemical features and performances in m-cresol methylation, Microporous and Mesoporous Materials, Vol. 66 (2003) p77-89	<input type="checkbox"/>
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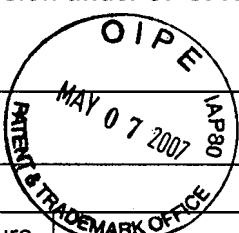
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41	ZHANG et al., Phosphorus anion-exchange characteristics of a pyroaurite-like compound, Inorganic Materials, Vol. 14 (1997)	<input type="checkbox"/>
42	MARCHI et al., Impregnation-induced memory effect of thermally activated layered double hydroxides, Applied Clay Science, Vol. 13 (1998) p35-48	<input type="checkbox"/>
43	ULIBARRI et al., Kinetics of thermal dehydration of some layered hydroxycarbonates, Thermochimica Acta, Vol. 135 (1988) p231-236	<input type="checkbox"/>
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45	BADREDDINE et al., Ion exchange of different phosphate ions into the zinc-aluminum-chloride layered double hydroxide, Materials Letters, Vol. 38 (1999) p391-395	<input type="checkbox"/>
46	SATO et al., Causticization of sodium carbonate with rock-salt type magnesium aluminum oxide formed by the thermal decomposition of hydrotalcite-like layered double hydroxide, J. Chem. Teck. Biotechnol., Vol. 57 (1993) p137-140	<input type="checkbox"/>
47	KOKOT et al., A rotating disk study on the rates of hydrotalcite dissolution at 25 °C, Pharmazie, Vol. 48 (1993) H. 4 p287-289	<input type="checkbox"/>
48	ROY et al., Anionic Clays: Trends in Pillaring Chemistry, Synthesis of Microporous Materials, Ch. 7, p108-169	<input type="checkbox"/>
49	TEZUKA et al., The synthesis and phosphate adsorptive properties of Mg(II)-Mn(III) layered double hydroxides and their heat-treated materials, Bull. Chem. Soc. Jpn., Vol. 77 (2004) p2101-2107	<input type="checkbox"/>
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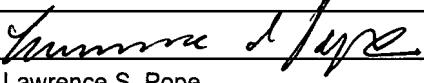
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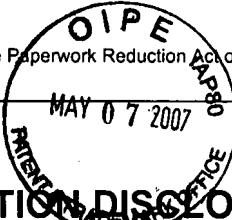
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1	FERREIRA et al., Thermal decomposition and structural reconstruction effect on Mg-Fe-based hydrotalcite compounds, Journal of Solid State Chemistry, Vo. 177 (2004) p3058-3069	<input type="checkbox"/>
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3	AMBROGI et al., Intercalation compounds of hydrotalcite-like anionic clays with anti-inflammatory agents, II: Uptake of diclofenac for a controlled release formulation, AAPS PharmSciTech, Vol. 3, No. 3 (2002) article 26	<input type="checkbox"/>
4	SEIDA et al., Removal of phosphate by layered double hydroxides containing iron, Water Research, Vol. 36 (2002) p1306-1312	<input type="checkbox"/>
5	LINARES et al., The influence of hydrotalcite and cancrinite-type zeolite in acidic aspirin solutions, Microporous and Mesoporous Materials, Vol. 74 (2004) p105-110	<input type="checkbox"/>
6	LAZARIDIS et al., Flotation of metal-loaded clay anion exchangers. Part I: the case of chromates, Chemosphere, Vol. 42 (2001) p373-378	<input type="checkbox"/>
7	LAZARIDIS et al., Flotation of metal-loaded clay anion exchangers. Part II: the case of arsenates, Chemosphere, Vol. 47 (2002) p319-324	<input type="checkbox"/>
8	RUBINSTEIN et al., The effect of granule size on the in vitro and in vivo properties of bendroflauzide tablets 5 mg, Pharm. Acta Helv., Vol. 52, Nr. 1/2 (1977)	<input type="checkbox"/>
9	USANA Technical Bulletin, Tablet Excipients, 6/99	<input type="checkbox"/>
10	International Specialty Products, Pharmaceuticals Solid Dosage Forms, 2004	<input type="checkbox"/>
11	REMUZZI et al., Hematologic consequences of renal failure, p2170-2186, The Kidney, Vol. II (5th ed. 1996)	<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <b>( Not for submission under 37 CFR 1.99)</b>	Application Number	10615797
	Filing Date	2003-07-10
	First Named Inventor	Roberts et al.
	Art Unit	1616
	Examiner Name	Alton N. Pryor
	Attorney Docket Number	40304772

	12	OE et al., Long-term use of magnesium hydroxide as a phosphate binder in patients on hemodialysis, Clinical Nephrology, Vol. 28, No. 4 (1987) p180-185	<input type="checkbox"/>
	13	O'DONOVAN et al., Substitution of aluminum salts by magnesium salts in control of dialysis hyperphosphataemia, The Lancet (April 19, 1986) p880-881	<input type="checkbox"/>
	14	MCCANCE et al., Absorption and excretion of iron, The Lancet (September 18, 1937) p680-684	<input type="checkbox"/>
	15	COOK, Adaptation in iron metabolism, Am. J. Clin. Nutr., Vol. 51 (1990) p301-308	<input type="checkbox"/>
	16	BOTHWELL, Overview and mechanisms of iron regulation, Nutrition Reviews, Vol. 53 (September 1995) p237-245	<input type="checkbox"/>

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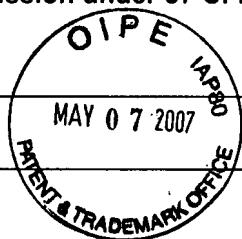
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
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Application Number	10615797
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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2007-05-08
Name/Print	Lawrence S. Pope	Registration Number	26,791

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